



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : Joan D. LEONARD et al.
SERIAL NO. : 10/726,029
FILING DATE : December 2, 2003
FOR : VACCINES FOR MYCOPLASMA BOVIS AND METHODS
OF USE
EXAMINER : Ford
GROUP ART UNIT: 1645

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DECLARATION OF JOAN D. LEONARD UNDER 37 C.F.R. § 1.132

I, Joan D. Leonard, declare the following:

1. I am a named co-inventor of the subject matter of the pending claims of United States Patent Application Serial No. 10/726,029.
2. I have read and understood United States Patent Application Serial No. 10/726,029, including the pending claims.
3. I am employed by Biomune Company, Lenexa, Kansas, the assignee of United States Patent Application Serial No. 10/726,029. Biomune Company is a subsidiary of CEVA Sante Animale, S.A., Libourne, France.

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Attorney Docket Number 12780/102

4. I received a Master of Science degree in Medical Microbiology from the University of Georgia in 1975. I received a Ph.D. in Microbiology from the University of Georgia in 1977. In addition, I was a post-doctoral fellow in molecular microbiology at the University of Alberta, Alberta, Canada in 1977-79. My curriculum vitae is attached hereto as Exhibit A.

5. I have worked for approximately 25 years in the field of bovine and other animal vaccines.

6. I am familiar with the scientific literature relating to bovine mastitis and attempts to develop vaccines against bovine mastitis as of the priority date of November 8, 1999 of United States Patent Application Serial No. 10/726,029 ("the art").

7. The art contained disclosures of the use of many different types of inactivating agents that could be used to inactivate microorganisms, in order to try to produce inactivated vaccines.

8. United States Patent Application Serial No. 10/726,029 describes some of these inactivating agents, at page 4, lines 13-17:

Examples of inactivating agents are: formalin, azide, freeze-thaw, sonication, heat treatment, sudden pressure drop, detergent (especially non-ionic detergents), lysozyme, phenol, proteolytic enzymes, propiolactone, Thimerosal (see United States Patent 5,338,543 Fitzgerald, et al.), and binary ethyleneimine (see United States Patent 5,565,205 Petersen, et al.).

9. Koski et al., 1976, J. Biological Standardization 4:151-154 (Koski)¹ describes the use of the inactivating agents phenol, formalin, and β -propiolactone.

¹ Koski was cited in the Office Action dated September 14, 2005 in connection with United States Patent Application Serial No. 10/726,029.

10. To the best of my knowledge, no art suggested that the use of any inactivating agent, including β -propiolactone, would produce a *Mycoplasma bovis* vaccine that could reduce the incidence of bovine mastitis.

11. There was a long felt but unsatisfied need in the art for a *Mycoplasma bovis* vaccine that could reduce the incidence of bovine mastitis.

12. For example, Heller et al., 1993, Vet. Microbiol. 37:127-133 (Heller)², when referring to methods of controlling the spread of *Mycoplasma bovis*-caused mastitis, did not mention that one should vaccinate to control mastitis but instead stated that culling is necessary. See page 127: "To control the spread of this disease, an early detection of the pathogen is crucial since the removal and culling of infected cows is necessary to prevent fresh infections."

13. Hanson, (September, 2001) Bovine Veterinarian 4-8 (Hanson I)³ and Hanson, (October, 2001) Bovine Veterinarian 12-20 (Hanson II)⁴, described methods to prevent mastitis or mitigate its effects, but the methods do not include vaccination, indicating that no effective vaccine was known to the art. This failure to mention vaccination is telling, since there clearly was recognition in the art that *Mycoplasma bovis*-caused mastitis was a serious problem. For example, Hanson I, at page 4, quotes a veterinarian as follows:

"*Mycoplasma* mastitis is a doubly insulting disease," says Blackmer. "Not only can it be remarkably contagious when it is present but it absolutely does not respond to antibiotic therapy. In fact, treatment can actually cause epidemics, because it frequently is spread by unsound intramammary therapy practices."

² A copy of Heller was enclosed with the Information Disclosure Statement filed April 8, 2004 for United States Patent Application Serial No. 10/726,029.

³ A copy of Hanson I was enclosed with the Information Disclosure Statement filed April 8, 2004 for United States Patent Application Serial No. 10/726,029.

⁴ A copy of Hanson II was enclosed with the Information Disclosure Statement filed April 8, 2004 for United States Patent Application Serial No. 10/726,029.

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14. If vaccination had been available, Heller, Hanson I, and Hanson II would have been expected to mention it, but they did not.

15. In view of the lack of teaching in the art as to which inactivating agents to use to produce a *Mycoplasma bovis* vaccine that could reduce the incidence of bovine mastitis, as well as the long felt need in the art for such a vaccine, I found it surprising, and one of ordinary skill in the art would have found it surprising, that such a vaccine could be produced.

16. Statements herein based on my own knowledge are true; statements herein based on information and belief are believed to be true. I acknowledge that willful false statements are punishable by fine or imprisonment as provided for by 18 U.S.C. § 1001 and may jeopardize the validity or enforceability of any patent that may mature from the present Application.

Signed March 13, 2006

Joan D. Leonard, Ph.D.
Joan D. Leonard, Ph.D.

EXHIBIT A

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Incidence

The number of new cases of a given disease during a given period in a specified population. It also is used for the rate at which new events occur in a defined population. It is differentiated from PREVALENCE, which refers to all cases, new or old, in the population at a given time.

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Joan D. Leonard, Ph. D.

Blomune Company
Executive Vice President
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Dr. Leonard holds both M.S. and Ph.D. Degrees in Medical Microbiology from the University of Georgia located in Athens, GA. Dr. Leonard was also a post-doctoral fellow in virus research at the University of Alberta in Edmonton, Alberta, Canada. While at these Universities her major research focus was viral and bacterial diseases of animals.

Dr. Leonard is currently employed by Blomune Company, Lenexa, KS, where she has served as Executive Vice President since January 1988. Dr. Leonard is responsible for the technical areas of Blomune including research and development of food producing animals, vaccine production, quality control and quality assurance, animal testing services, and Regulatory Affairs (government compliance).

For seven years prior to being employed by Blomune, Dr. Leonard was Manager of the Poultry Health Services Laboratory at Perdue Farms, Salisbury, MD, one of the five largest poultry production operations in the USA. Activities included research and development of poultry vaccines, live poultry production disease research, and managing a poultry disease diagnostic laboratory. Before joining Perdue Farms in 1981, Dr. Leonard was employed as the avian virologist at the Georgia Poultry Laboratory in Oakwood, Georgia.

Exhibit A
Declaration of Joan D. Leonard
U.S. Serial No. 10/726,029